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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,441	11/10/2003	Gerald D. Cagle	2399 F US	4603

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EXAMINER	
DAVIS, RUTH A	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,441	CAGLE ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 58-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/04;2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 14 - 57 in the reply filed on October 20, 2006 is acknowledged. Additionally, the species of trypsin, glycerin, poly(oxyethylene)-poly(oxypropylene) block copolymers, benzalkonium halides, and citrate are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction is therefore maintained and made **FINAL**. Claims 1 – 13 and 58 – 72 are withdrawn as being drawn to non-elected subject matter. Claims 14 – 57 have been considered on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 14 – 38 and 41 – 57 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Asgharian et al. (US6139646 A).

Applicant claims a composition comprising a cerumenolytically acceptable enzyme in an amount effective to assist in removing human cerumen; and an aqueous otologically acceptable vehicle. The enzyme is a protease, specifically a proteolytic enzyme, trypsin, that may be microbially derived, that is alkyl trypsin, more specifically is methyl trypsin. The vehicle comprises a demulcent, surfactant, preservative or buffer which are glycerin, poly(oxyethylene)-poly(oxypropylene) block copolymers, benzalkonium halides and citrate, respectively. The methyl trypsin is present at about 50 – 500 AU/ml. The composition further comprises an enzyme stabilizing agent that is a monomeric polyols, specifically glycerin; further comprises a bicarbonate in an amount to assist in removing human cerumen, specifically sodium bicarbonate. Applicant additionllay claims a 2 part composition comprising a cerumenolytically acceptable enzyme in an amount effective to assist in removing human cerumen; and an aqueous otologically acceptable vehicle; wherein the 2 parts are maintained separately and mixed before administration. The vehicle further comprises a bicarbonate in an amount effective to assist removal of human cerumen, the enzyme is a protease, proteolytic enzyme, trypsin, is microbially derived, specifically is an alkyl trypsin, more specifically methyl trypsin. The bicarbonate is sodium bicarbonate; and the composition further comprises a demulcent, surfactant, preservative, buffer, enzyme stabilizing agent that is monomeric polyols. The first and second parts are packaged in separate bottles; the first and second parts are packaged in a device with a first container receiving the first part and a second container receiving the second part; and a non-

permeable membrane separating the containers; wherein the membrane may be torn to allow mixing of the first and second parts.

Asgharian teaches a composition comprising an alkylated trypsin (cerumenolytically acceptable enzyme) (abstract) and water (aqueous otologically acceptable vehicle) (claims). Specifically the enzyme is methyl trypsin (col.4 line 23-43), which may be microbially derived. The composition further comprises buffers, surfactants, preservatives and enzyme stabilizers (col.6) to include citrate, sodium bicarbonate (col.6), monomeric polyols such as glycerol (glycerin) (also a demulcent) (col.7), benzalkonium halides (col.10), and block copolymers/pluronics (copolymers of poly(oxyethylene)-poly(oxypropylene)) (col.11). The enzyme is present at 1 – 100 PAU/ml (or 1 – 100 AU/ml, as described by applicant in spec p.13-14) (col.9). Asgharian teaches the composition in two parts, specifically a part 1 comprising the enzyme and part 2 comprising the diluting composition (or vehicle), whereby the parts are maintained separately until use (col.9). Specifically, 2 compartments (or containers) are maintained whereby a mixing chamber mixes the 2 parts together just prior to use (col.9). The reference teaches the containers of WO 98/25650 may be uses which teaches a breakaway membrane that is torn (claims).

The reference does not identify the composition effective for removing human cerumen. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when

applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

4. Claims 14 – 18, 21 – 25, 27, 29, 31 and 34 – 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chowan et al. (WO 96/40854).

Applicant claims a composition comprising a cerumenolytically acceptable enzyme in an amount effective to assist in removing human cerumen; and an aqueous otologically acceptable vehicle. The enzyme is a protease, specifically a proteolytic enzyme, trypsin, that may be microbially derived. The vehicle comprises a demulcent, surfactant, preservative, buffer, glycerin, benzalkonium halides. The composition further comprises an enzyme stabilizing agent that is a monomeric polyols, specifically glycerin,

Chowan teaches a composition comprising trypsin (cerumenolytically acceptable enzyme) or micbially derived enzymes (p.9) and glycerol (glycerin, a demulcent) (aqueous otologically acceptable vehicle) (p.7, claims). The composition further comprises buffers, preservatives (p.15), surfactants (p.17), enzyme stabilizers and/or benzalkonium halides (p.15)

The reference does not identify the composition effective for removing human cerumen. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when

applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 39 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asgharian.

Applicant claims a composition comprising a cerumenolytically acceptable enzyme in an amount effective to assist in removing human cerumen; and an aqueous otologically acceptable

vehicle. The composition further comprises a bicarbonate in an amount to assist in removing human cerumen, specifically sodium bicarbonate present at about 0.5 – 15%. The enzyme I methyl trypsin and is present at about 50 – 500 AU/ml.

Asgharian teaches a composition comprising an alkylated trypsin (cerumenolytically acceptable enzyme) (abstract) and water (aqueous otologically acceptable vehicle) (claims). Specifically the enzyme is methyl trypsin (col.4 line 23-43). The composition further comprises sodium bicarbonate (col.6). The enzyme is present at 1 – 100 PAU/ml (or 1 – 100 AU/ml, as described by applicant in spec p.13-14) (col.9).

The reference does not specifically teach the composition comprising 0.5 – 15% sodium bicarbonate. However, Example 4 clearly discloses sodium bicarbonate in an amount of at least 0.2%. Since the amounts of the other components (i.e. lactose) are variable, the amount of the sodium bicarbonate may also vary in terms of its percent amount. Thus, in following the teachings of the cited reference, one of ordinary skill in the art would have been motivated to optimize the amount of sodium bicarbonate as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the reference to optimize the percent amount of sodium bicarbonate with a reasonable expectation for successfully obtaining an enzyme composition.

The reference does not identify the composition effective for removing human cerumen. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to

create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651

January 5, 2007